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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,124	10/20/2003	Mark H. Falahee	FLH-10902/29	2910
25006	7590	10/29/2007		
GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 10/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/689,124

Applicant(s)

FALAHEE, MARK H.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received 07 August 2007.

The examiner acknowledges the amendments made to the claims.

Claim Objections

1. Claims 13 and 15 are objected to because of the following informalities: On line 2 of Claim 13 it reads "the marker of Figure 1" although there were no drawings submitted. The examiner speculates that applicant meant "Claim 1" rather than "Figure 1" and therefore "the marker of Figure 1" should be changed to --the marker of Claim 1-- Claim 15 is a duplicate of Claim 14 and therefore should be cancelled or contain added limitations. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 2 recites the limitation "the ink" on line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3734

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-8 and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by **Palasis** (U.S. Patent No. **6,689,103**).

Claims 1-8, 10-13: Palasis discloses a marker comprising a housing **22** in the form of a marking pen and a reservoir **26** in the housing that is filled with a substance or "contrast solution" ink which, when dispensed through the marking pen is radiopaque, the ink being visible to the human eye and capable of marking human skin or commercially available surgical film. The substance includes a heavy metal, such as barium and is primarily a liquid and is erasable, biocompatible, and non-toxic. Palasis discloses providing the marking pen of Claim 1 and indicating an operative site using the marking pen and subjecting the site to x-ray exposure ("fluoroscopic equipment") for the purpose of comparing the indication to one or more internal structures associated with the procedure (Figure 1, col. 7, lines 48 to col. 8, line 15, col. 9, lines 1-4, col. 11, lines 12-23).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Palasis** (U.S. Patent No. **6,689,103**) in view of **DeSena** (U.S. Patent No. **6,198,807**).

Claims 9 and 14: Palasis discloses the claimed device except for the substance being primarily a powder and the step of indicating an operative site using the marking pen includes marking a surgical film and erasing an indication if not optimized for the procedure.

DeSena teaches a radiopaque substance being primarily a powder and the step of indicating an operative site using the marking pen includes marking a surgical film **36** (Figure 5, col. 3, lines 45-60, col. 6, lines 18-48, col. 7, lines 22-39). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a powdered substance and marking a surgical film, as taught by DeSena, since it was known in the art that powder is minimally invasive and easily removed from the skin or surgical film when undesired, and that using a marked surgical film is also minimally invasive and easily removed from the surgical site being x-rayed. Although DeSena does not teach erasing an indication if not optimized for the procedure, it would have been obvious to one of ordinary skill in the art since it was known in the art that the ink is erasable and commonplace errors in marking may be conveniently corrected by erasing them.

Response to Arguments

8. Applicant's arguments filed 07 August 2007 have been fully considered but they are not persuasive.

9. The applicant argues that Palasis is entirely unrelated to the instant invention and that Palasis resides in a fluid delivery system and does not disclose any type of "marker," or marking skin or surgical film. The examiner asserts that based on the recitation of the claims 1-8 and 10-13, Palasis discloses a marking pen, in that it dispenses a radiopaque contrast solution, and therefore marks, indicates or visualizes the vascular pathway. The device would be capable of marking skin or surgical film.

10. In regards to claims 9 and 14, the applicant is unclear about the examiner's assertion that it would have been obvious to provide Palasis with a powdered substance and mark a surgical film since it was known in the art that powder is minimally invasive, and that marked surgical film is minimally invasive and easily removed. The examiner would like to clarify that using powder and surgical film is minimally invasive and does not injure or necessarily penetrate tissue.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER